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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/776,311	02/11/2004	Anthony J. Kinney	BB1538USNA	4023

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EXAMINER	
FOX, DAVID T	

ART UNIT	PAPER NUMBER
1638	

NOTIFICATION DATE	DELIVERY MODE
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

PTO-Legal.PRC@usa.dupont.com

Office Action Summary	Application No.	Applicant(s)	
	10/776,311	KINNEY ET AL.	
	Examiner	Art Unit	
	David T. Fox	1638	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *14 March 2008*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,11,12,16-18,21-28,140 and 141* is/are pending in the application.

4a) Of the above claim(s) *21-25 and 140* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,11,12,16-18,26-28 and 141* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *21 September 2006* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

Withdrawal of Finality

In view of the following new grounds of rejection, necessitated by newly found art, finality is hereby WITHDRAWN. Applicant's amendment of 14 March 2008 has been entered. The delay in prosecution is regretted.

Applicant's amendment of 14 March 2008 has overcome the claim objection of record.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Obviousness-Type Double Patenting

Claims 1, 11-12, 16-18, and 26-28 remain, and new claim 141 is provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claim 1 of copending Application No. 11/624,777. Although the conflicting claims are not identical, they are not patentably distinct from each other because of the reasons presented on page 2 of the Office action of 01 February 2008.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Enablement

Claims 1, 11-12, 16-18, and 26-28 remain, and new claim 141 is rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for claims limited to oilseed plants which produce mature seeds with oil comprising at least 1% of at least one of EPA, DPA or DHA, wherein said plants have been transformed with at least two desaturase genes and at least one corresponding elongase gene from

the same pathway as at least one of the desaturase genes; does not reasonably provide enablement for claims broadly drawn to any oilseed plant of any genotype which produces the claimed levels of the claimed fatty acids. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims, as stated on page 3 of the Office action mailed 01 February 2008.

Written Description

Claims 1, 11-12, 16-18 and 26-28 remain, and new claim 141 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention, as stated on pages 4-5 of the Office action mailed 01 February 2008.

Applicant's arguments filed 14 March 2008 have been fully considered but they are not persuasive. Applicant urges that the rejections under 35 USC 112, first paragraph, are improper, given the obtention by many workers of transformed oilseed plants with seed oil exhibiting the claimed levels of the claimed fatty acids, when different transgenes are used. The Examiner maintains that all of the transgenes used by the other workers fell within the desaturase and elongase transgene categories specified by the Examiner, while the instant claims are completely silent with regard to the identity of any putative transgene or the enzyme encoded by it. Applicant has not demonstrated a representative number of species for the genus which encompasses all

transgenes encoding all gene products, and which also encompasses plants with mutated endogenous genes but with no transgenes. Furthermore, Applicant has not demonstrated the conserved sequences in the broad genus of transgenes or mutated endogenous genes which are correlated with the function of producing the claimed fatty acids in the claimed proportions.

Obviousness

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1, 16 and 26 are rejected under 35 U.S.C. 103(a) as being unpatentable over Knutzon et al (US 6,075,183 issued June 2000), in view of ABBOTT LABORATORIES (WO 02/08401 effectively filed July 2000), further in view of

BIORIGINAL FOOD & SCIENCE CORPORATION (WO 02/26946 effectively filed September 2000), all references submitted by Applicant.

The claims are broadly drawn to a transgenic oilseed plant including Brassica plants, which produce seeds which comprise the transgene and which contain oil comprising at least 1% of at least one polyunsaturated fatty acid (PUFA) having at least 20 carbon atoms and at least five carbon-carbon double bonds.

Knutzon et al teach the various enzymatic pathways for producing PUFAs with at least 20 carbon atoms and at least five carbon-carbon double bonds, wherein untransformed plants are only able to produce polyunsaturated fatty acids with 18 carbons such as linoleic acid (2 double bonds) and linolenic acid (3 double bonds), wherein a combination of elongase, delta 6 desaturase, delta 5 desaturase and delta 4 desaturase are required to convert linoleic acid to gamma linolenic acid which is ultimately converted into the omega-6 PUFA of DPA via a dihomogamma linolenic acid (DGLA) precursor; wherein PUFAs such as DPA are precursors for compounds like prostaglandins which are essential for human health and development, wherein transgenic plants producing PUFAs in their seed oil are useful for nutritional supplements or pharmaceutical compositions, wherein genes encoding enzymes including delta 5 and delta 6 desaturases were operably linked to a seed-specific napin promoter and introduced into transgenic Brassica plants, and wherein said transgenic Brassica plants produced seeds with oil comprising over 11% of new fatty acids including the DGLA precursor, and wherein the combination of desaturase and elongase transgenes was suggested for the production in plants of PUFAs with at least

20 carbons and at least 5 carbon-carbon double bonds (see, e.g., Figures 1-2; column 1 through column 2, line 45; column 3, lines 1-19; column 4, line 55 through column 5, line 12; column 19, line 27 through column 26).

Knutzon et al do not teach the recovery of transgenic oilseed plants which produce at least 1% PUFAs with at least 20 carbon atoms and at least 5 carbon-carbon double bonds.

ABBOTT LABORATORIES teaches the desirability of PUFAs including omega-6 DPA for pharmaceutical or nutritional compositions, the isolation of elongase genes necessary for the production of polyunsaturated 20-carbon fatty acids in plants, and suggests plant transformation including Brassica transformation with said elongase gene under the control of a seed-specific promoter for the production of said PUFAs in seed oils, wherein co-transformation with a gene encoding a delta 4 desaturase would also be needed for the production of omega-6 DPA (see, e.g., Abstract; Figure 1; page 1, bottom paragraph; page 2, top and bottom paragraphs; page 5, lines 15-23; page 6, lines 1-6; page 7, lines 1-6 and 24-31; pages 8-9; page 11, lines 6-13 and 24-31; page 12, line 17 through page 13; page 53, lines 21-27; page 54, line 15 through page 55, line 18).

BIORIGINAL FOOD & SCIENCE teaches the isolation of a delta 4 desaturase gene which is involved in the synthesis of omega-6 DPA, the desirability of plant transformation with a variety of desaturase genes for the production of PUFAs in seed oil, the transformation of Brassica with said delta 4 desaturase gene and the function of the encoded enzyme to convert an exogenously supplied substrate, the transformation

of Brassica with a delta 5 desaturase gene under the control of a seed-specific napin promoter wherein the transgenic seeds produced up to 9.4% of new PUFAs in their seed oil, and the transformation of Brassica with a delta 6 desaturase gene under the control of the napin promoter wherein the transgenic seeds produced up to 38% of gamma linolenic acid which is a precursor to PUFAs including omega-6 PUFAs (see, e.g., Figures 16 and 21-22; page 1, line 31 through page 3, line 7; page 3, line 34 through page 4, line 5; page 7, lines 1-19; page 8, lines 26-30; page 42, line 26 through page 43, line 2; page 48, bottom paragraph; page 49, bottom paragraph through page 50, top paragraph; page 51, lines 9-22).

It would have been obvious to one of ordinary skill in the art to utilize the method of Brassica transformation with the delta 5- and delta 6- desaturase genes under the control of the seed-specific napin promoter for the production of novel PUFAs in the seed oil of transgenic plants as taught by Knutzon et al, and to modify that method by incorporating the elongase genes taught by ABBOTT LABORATORIES under the control of a seed-specific promoter, and to further modify that method by incorporating the delta 4 desaturase gene taught by BIORIGINAL FOOD & SCIENCE under the control of the seed-specific napin promoter, to obtain transgenic Brassica seeds producing oil with at least 1% of omega-6 DPA, as suggested by each reference. Given the high levels of novel PUFAs in transgenic seeds taught by Knutzon et al, ABBOTT LABORATORIES and BIORIGINAL FOOD & SCIENCE, the instantly claimed percentage of novel PUFA would be reasonably expected.

Claims 1, 11-12, 16-18, 26-28 and 141 are rejected under 35 U.S.C. 103(a) as being unpatentable over Knutzon et al (US 6,075,183) in view of ABBOTT LABORATORIES (WO 02/08401 effectively filed July 2000), further in view of each of Mukherji et al (US 7,211,656 effectively filed January 2002) or Browse et al (US 6,884,921 effectively filed February 1997).

The claims are broadly drawn to transgenic oilseed plants including Brassica plants which comprise in their seed oil at least 1% of an omega-3 PUFA with at least 20 carbons and at least 5 double bonds, including EPA.

Knutzon et al teach Brassica plant transformation with delta-5 and delta-6 desaturase genes under the control of the seed-specific napin promoter for the production of high levels of novel PUFAs in seed oil, and suggest plant transformation with other elongase and desaturase genes for the production of many different types of PUFAs in transgenic seed oil, as discussed above. Knutzon et al also teach that EPA is produced from arachidonic acid (ARA) by a delta-17 desaturase, wherein ARA is produced by subjecting linoleic acid to the combined action of elongase and delta-6 and delta 5 desaturases, and wherein omega-3 PUFAs such as EPA also have beneficial pharmaceutical and nutritional applications (see, e.g., Figure 2; column 1, lines 13-15 and 25-27; column 3, lines 17-18).

Knutzon et al do not teach transgenic plants producing at least 1% omega-3 PUFAs with at least 20 carbons and at least 5 double bonds, such as EPA, in their seed oil.

ABBOTT LABORATORIES teaches the isolation of several elongase genes and suggests plant transformation therewith under the control of a seed-specific promoter, as discussed above. ABBOTT LABORATORIES also teach the advantages of EPA as a nutritional and pharmaceutical component, that the combination of elongase and delta-5 elongase is required for EPA production, and suggest the use of a transgene encoding another desaturase including a delta-17 desaturase (see, e.g., page 1, lines 22-24; page 8, lines 15-18; page 13, lines 4-7; page 55, lines 3-5 and 10-12).

Mukherji et al teach that omega-3 desaturase and delta-17 desaturase are synonyms, that this enzyme is required for the production of EPA which has nutritional and pharmaceutical applications, that yeast transformed with an isolated gene encoding this enzyme and a delta-5 desaturase gene produced EPA, and that yeast transformed with this gene alone produced EPA when exposed to a precursor; and also suggest oilseed transformation including Brassica transformation with a seed-specific promoter for the production of EPA in transgenic seed oil (see, e.g., Figures 1- 2; columns 1-4; column 5, lines 45-49; column 6, lines 8-37; column 7, lines 1-5; column 15, lines 41-48; column 16, lines 1-20 and 60-66; column 32, lines 5-44; column 33, lines 1-40; column 35, line 24 through column 37, line 12).

Browse et al teach the isolation of a gene encoding an omega-3 desaturase enzyme which desaturates ARA to EPA by introducing a double bond at carbon position 17, wherein the gene was introduced into transgenic plants and produced high levels of EPA when sprayed with an ARA substrate, wherein EPA is useful as a nutritional or pharmaceutical supplement, and also suggest Brassica plant transformation with the

desaturase gene under the control of a seed-specific promoter (see, e.g., Figure 1; column 1, lines 24-42; column 2, lines 13-22; column 3, lines 13-45; column 7, lines 6-20; column 12, lines 15-25 and 45-49; column 15, lines 18-21; column 16, lines 46-67; column 17, lines 26-30 and 41-60; column 18, lines 26-30 and 40-67; column 19, lines 1-10; column 20, lines 9-20; claims 1-4 and 6-15).

It would have been obvious to one of ordinary skill in the art to utilize the method of Brassica transformation with the delta 5- and delta 6- desaturase genes under the control of the seed-specific napin promoter for the production of novel PUFAs in the seed oil of transgenic plants as taught by Knutzon et al, and to modify that method by incorporating the elongase genes taught by ABBOTT LABORATORIES under the control of a seed-specific promoter, and to further modify that method by incorporating the omega 3/delta 17 desaturase genes taught by each of Mukherji et al or Browse et al under the control of a seed-specific promoter such as the napin promoter for the production of EPA in the oil of the transgenic Brassica seeds, as suggested by each reference. Given the high levels of novel PUFA produced by the transgenic organisms taught by each of Knutzon et al, Mukherji et al or Browse et al, one of ordinary skill in the art would have reasonably expected the instantly claimed levels of EPA in the seed oil; as influenced by the highly expressed seed-specific napin promoter and the high proportion of oil in Brassica seeds.

Conclusion

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David T. Fox whose telephone number is (571) 272-0795. The examiner can normally be reached on Monday through Friday from 10:30AM to 7:00PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anne Marie Grunberg, can be reached on 571-272-0975. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

March 26, 2008

/David T Fox/

Primary Examiner, Art Unit 1638